DOSIsoft K112723

FEB - 8 2012

Premarket Notification [510(k)] Summary
Tab 4

Tuesday, September 6th, 2011

Trade Name: EPIgray

Classification Name: Accelerator, Linear, Medical, IYE (per 21 CFR section 892.5050)

Manufacturer's Name: DOSIsoft SA
Address: 45-47 avenue Carnot
94230 CACHAN – France

Corresponding Official: Hanna Kafrouni, Ph.D.
Title: CEO

Telephone: 33 1 41 24 26 26
Fax: 33 1 41 24 26 28

Predicate: Dosimetry Check with Exit Dose from Math Resolutions, LLC (K 101503)

Device Description: EPIgray is comprehensive software that allows the user to perform an in-vivo dosimetry by means of imaging device such as an Electronic Portal Imaging Device (EPID). The product is composed of: EPIgray workstation and In-Vivo Manager tool. Epigray workstation is an extension of an already cleared product: ISOgray planning system (K103146). It uses only two modules of the previously approved system: Information module and Exacor module. In Vivo manager software is a web application intended for in-vivo measurements management. In particular, it allows to retrieve, on a web browser, the result of dose reconstruction by EPIgray workstation based on EPID.

Intended Use: EPIgray is a software dedicated for error detection in dose delivery and patient positioning during X-ray high energy radiation therapy. EPIgray uses images acquired from a portal imaging system (EPID) to reconstruct the dose in the patient. The comparison between the reconstructed and the planned dose, activates warnings and allows a follow-up of the dose actually given to the patient.

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Clinical tests: Clinical trials were not performed as part of the development of this product. Clinical testing is not advantageous in demonstrating substantial equivalence or safety and effectiveness of the device since testing can be performed such that no human subjects are exposed to risk. However, algorithm evaluation was performed by Medical Physicists team using measured data in a clinical facility. Evaluation summary is available in tab 13 of this submission.

Non-Clinical tests: Verification tests were written and executed internally to validate that the system works according to the requirement. The documentation includes system level test pass/fail criteria and a summary of the test results. It is available in the Verification and Validation section from Tab 12, Sub Tab 6.

DOSISOFT SA
45/47, avenue Carnot
94230 CACHAN
S.A. capital 500 000 €

Tél. : 01 41 24 26 26
Fax : 01 41 24 26 28

info@dosisoft.com
www.dosisoft.com

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DOSIsoft SA
% Mr. Robert J. Morton
President
Quality and Regulatory Services, Inc.
1244 Fairway Valley Court
LINCOLN CA 95648-8489

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Re: K112723
Trade/Device Name: EPIgray
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: January 18, 2012
Received: January 27, 2012

Dear Mr. Morton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

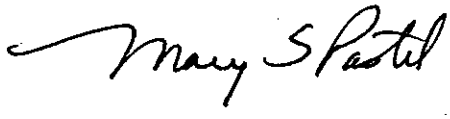
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Tab 3

Indication for Use Statement

510(k) Number (if known): K112723

Device Name: EPIgray

Indications for Use:

EPIgray is a software to be used by radiation oncologist and medical physicist to detect errors in the delivery of high energy X-rays during the course of patient treatment. This product verifies if the reconstructed dose, computed by the system, is in agreement with the planned dose given by the treatment planning system. This product uses the measurements performed by an Electronic Portal Imaging Device (EPID). This product uses the prescription computed by the treatment planning system. This product in not used to give a prescription of the radiation therapy.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112723